

**REMARKS**

This paper is submitted in response to the Office Action mailed November 18, 2003. Following this amendment, claims 1-12, 15, and 22-24 are pending. Claims 13, 14, and 18 have been cancelled herein, to advance prosecution of this application and without prejudice to the prosecution of their subject matter in other patent applications. Claim 12 has been amended. Support for the amendment can be found throughout the specification and claims as originally filed and there is no new matter added as a consequence of the amendment to the claim.

Claims 1-11, 15 and 22-24 are allowed.

**The Rejection under 35 U.S.C. § 112, ¶1 Should Be Withdrawn**

Claim 18 is rejected under 35 U.S.C. §112, first paragraph, because the specification, while being enabling for introducing a nucleotide sequence into target cells *in vitro* for the expression of a nucleotide sequence, allegedly does not provide enablement for a method of gene therapy.

Applicants maintain, for reasons set forth in their Amendment dated August 27, 2003, that claim 18 is enabled. However, in order to place this application in order for allowance, Applicants have cancelled claim 18, without prejudice to the prosecution of its subject matter in other patent applications. Therefore, the Examiner's rejection of claim 18 is rendered moot.

**The Rejections under 35 U.S.C. § 112, ¶2 Should Be Withdrawn**

Claims 12 and 14 are rejected under U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 12 is allegedly indefinite because it is unclear if the claim is

directed to a provirus that results from the infection of a target cell solely with the retroviral vector of claim 1 or if it includes provirus that can be acquired from a host cell that is also infected with an endogenous retrovirus. Claim 14 is allegedly indefinite for the recitation of the limitation "RNA of a retroviral vector." The Examiner alleges that it is unclear if the RNA includes any portion of an RNA or if it must include the entire reverse transcribed sequence of the claimed vector.

Applicants have amended claim 12 to recite "recombinant retroviral particle," as suggested by the Examiner. Therefore, Applicants submit that amended claim 12 is not indefinite and request withdrawal of the rejection of the claim under U.S.C. §112, second paragraph.

Without conceding that the Examiner's contentions are correct, Applicants have cancelled claim 14, without prejudice to the prosecution of its subject matter in other patent applications. Therefore, the Examiner's rejection of claim 14 is rendered moot.

#### The Rejection under 35 U.S.C. § 101 Should Be Withdrawn

Claims 12 and 13 are rejected under 35 U.S.C. § 101, because the invention is allegedly directed to non-statutory subject matter. With regard to claim 12, the Examiner alleges that the claimed retroviral provirus may result from a retrovirus that is already endogenous to the host cell and thus not be the result of the specific retroviral particle containing the instantly claimed vector. As indicated above and suggested by the Examiner, Applicants have amended claim 12 to insert "recombinant" before "retroviral particle." Therefore, Applicants submit that amended claim 12 is not directed to non-statutory subject matter and is allowable.

With regard to claim 13, the Examiner alleges that the mRNA produced by the provirus could be an endogenous RNA, since there is no chemical distinction between an mRNA produced from the retroviral particle/vector of the instantly claimed invention and an mRNA endogenous to any host cell so that the mRNA is non-statutory as not demonstrating the presence of the 'hand-of-man.' Without conceding that the Examiner's contentions are correct, Applicants have cancelled claim 13, without prejudice to the prosecution of its subject matter in other patent applications. Therefore, the Examiner's rejection of claim 13 is rendered moot.

The Rejections under 35 U.S.C. § 102(b) Should Be Withdrawn

Claims 13 and 14 are rejected under 35 U.S.C. § 102(b), as allegedly anticipated by Alexander et al., 1997, Biotechniques 23:64-66 ("Alexander"). The Examiner contends that Alexander teaches the expression of EGFP mRNA from a retroviral vector containing the EGFP gene under the control of the SV40 early promoter, which is allegedly not distinguishable from the provirus recited in claim 13. The Examiner also contends that Alexander teaches an RNA including a 3' LTR and 5' LTR of a retroviral vector, which is allegedly not distinguishable from the RNA recited in claim 14.

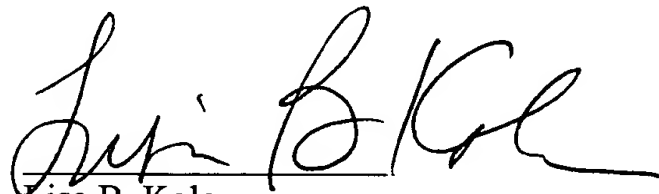
As indicated above in the prior sections, claims 13 and 14 have been cancelled, without prejudice. Therefore, the Examiner's rejection of claims 13 and 14 is rendered moot.

**CONCLUSION**

In view of the foregoing amendments and remarks, Applicants respectfully request withdrawal of the outstanding rejections and allowance of the pending claims.

Applicants request a three month extension of time and enclose herewith the requisite fee as set forth in 37 C.F.R. § 1.17(a)(3). Applicants do not believe that any additional fee is required in connection with the submission of this document. However, should any fee be required, or if any overpayment has been made, the Commissioner is hereby authorized to charge any fees, or credit or any overpayments made, to Deposit Account 02-4377. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Lisa B. Kole', written over a horizontal line.

Lisa B. Kole

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